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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,677	04/02/2004	Kinh-Luan (Lenny) Dao	03-302	9708

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/816,677	DAO ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,10-13,15,17-21 and 23-46* is/are pending in the application.

4a) Of the above claim(s) *2-4,12,13,15,20,21,24,25,27-30,33-38,44 and 45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,10,11,17-19,23,26,31,32,39-43 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment filed 01/22/2009.

Claims 1-42 previously presented.

Claims 6-9, 14, 16, 22 have been canceled.

Claims 43-46 have been added by the present amendment.

Claims 1-5, 10-13, 15, 17-21, 23-46 are pending.

1. Newly submitted claims 44 and 45 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: in the reply filed 12/03/2007 applicant elected the species stent and the balloon was withdrawn from reconsideration.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 44 and 45 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. This application contains claims 2-4, 12, 13, 15, 20, 21, 24, 25, 27-30, 33-38, 44 and 45 drawn to an invention nonelected with traverse in the reply filed on 12/03/2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1, 5, 10, 11, 17-19, 23, 26, 31, 32, 39-43, 46 are included in the prosecution.

Response to Election/Restrictions

3. Applicants argue that claim 10 is overlapping in scope with claims 12 and 13 and not mutually exclusive and not burdensome to be examined. In response to this argument, it is argued that searching for microparticles is different from searching for two populations of microparticles that are of different composition from each other and different from searching for two populations of microparticles that have different size distribution, and the prior art that anticipates the genus microparticles may not anticipate the species of microparticles of two populations as recited by claims 12 and 13 as evident by the recited prior art US '617 that anticipated the microparticles but not the species comprising two population of microparticles. Additionally, it is argued that the search system and the focus of the invention are completely different, requiring an undue burden on the patent examiner. While searches may seem to be overlapping, however extensive since the patent examiner searches the databases mostly literally.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The Species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph. The same apply on the other species.

The requirement is still deemed proper and is therefore made FINAL.

The following new ground of rejections is necessitated by applicants' amendment:

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 5, 10, 17-19, 23, 26, 31, 32, 40, 41, 43 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,491,617 (617).

US '617 disclosed medical device including stent of biocompatible material comprising plurality of exogenous storage structure, that reads on microparticles, and particles of therapeutic agent on the surface of the device (abstract; col.5, lines 3-10, 22-24). The reference teaches the active agents are on the surface of the

microparticles, so is not embedded into the microparticles as required by the instant claims. The reference further disclosed that plurality of particles of therapeutic agents can be applied to different portions of the biocompatible material (col.16, line 54 till col.17, line 26), this teaching also reads on therapeutic agent and microparticles applied to different portion of the device. The therapeutic particles are deposited on the surface of the device by dipping the device in dispersion of the particles, followed by drying (col.16, lines 45-46), i.e. not spray dried microparticles and reads on solvent assisted adhesive as disclosed by applicants. The therapeutic particles are bound to the device surface using same method of binding the exogenous storage structure including using cross-linker (col.12, lines 17-60), which all disclosed by applicants in pages 4-5 as adhesives. The therapeutic agents include microscopic macromolecules including proteins, polypeptides and nucleic acids having high molecular weight greater than 25,000 amu (col.10, lines 53-63).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 5, 10, 11, 17-19, 23, 26, 31, 32, 40, 41, 43 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,491,617 (617).

US '617 teaches medical device including stent of biocompatible material comprising plurality of exogenous storage structure, that reads on microparticles, and particles of therapeutic agent on the surface of the device (abstract; col.5, lines 3-10, 22-24). The reference teaches the active agents are on the surface of the microparticles, so is not embedded into the microparticles as required by the instant claims. The reference further disclosed that plurality of particles of therapeutic agents can be applied to different portions of the biocompatible material (col.16, line 54 till col.17, line 26), this teaching also reads on therapeutic agent and microparticles applied to different portion of the device. The therapeutic particles are deposited on the surface of the device by dipping the device in dispersion of the particles, followed by drying (col.16, lines 45-46), i.e. not spray dried microparticles and reads on solvent assisted adhesive as disclosed by applicants. The therapeutic particles are bound to the device surface using same method of binding the exogenous storage structure including using cross-linker (col.12, lines 17-60), which all disclosed by applicants in pages 4-5 as

adhesives. The therapeutic agents include microscopic macromolecules including proteins, polypeptides and nucleic acids having high molecular weight greater than 25,000 amu (col.10, lines 53-63).

The prior art recognized the presence of therapeutic agent are on the surface of the microparticles on the surface of the stent. However, the reference is silent regarding the therapeutic agent is not embedded within the microparticles. It has been held that configuration is a matter of choice which a person having ordinary skill in the art would have found obvious absent evidence that the specific configuration was significant. See *In re Daily*; 357 F.2d 669, 149 USPQ 47 (CCPA 1966). It has been also held that the use of one piece construction instead of multiple would be merely a matter of obvious engineering choice. See In re Larson, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965). This recitation does not impart patentability to the claims absence of showing superior and unexpected results obtained from having the particles separate from the therapeutic agent.

Regarding claim 11, US '617 teaches microscopic molecules, however, the reference does not explicitly teach the particle size as instantly claimed by claim 11.

Applicants failed to show unexpected results obtained from the claimed particle diameters, therefore, it would have been obvious to one having ordinary skill in the ad at the time the invention was made to have particles on the adhesive layer covering medical devices with a diameter between 0.1 to 50 μm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the

optimum or workable ranges and dimensions involves only routine skill in the art. *In re Aller* 105 USPQ 233.

9. Claims 39 and 42 are rejected under 35 U.S.C. 103(a) as being obvious over US '617 in view of US 6,545,097 ('097).

The teachings of US '617 are previously discussed as set forth in this office action.

Although US '617 teaches therapeutic agents coated on the medical device, however, the reference does not teach covering the therapeutic agent by disintegrable layer as instantly claimed by claimed 39 and 42.

US '097 teaches implantable device such as stent covered with biocompatible degradable polymer comprising therapeutic agent and covered with sheath to prevent premature therapeutic agent release (abstract; col.5, lines 19-23; col.14, lines 20-26).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide medical device such as stent covered with therapeutic agent and particles as disclosed by US '617, and further provide biocompatible degradable polymer covering over the therapeutic agents and the microparticles as disclosed by US '097 because US '097 teaches that such covering prevents premature therapeutic agent release, with reasonable expectation of having stent covered with therapeutic agent and microparticles and further covered with biocompatible degradable polymer covering wherein premature release of the therapeutic agents is successfully prevented.

Response to Arguments

10. Applicant's arguments filed 01/22/2009 have been fully considered but they are not persuasive. Applicants traverse the anticipatory and obviousness rejection over US '617 by arguing that the reference does not teach that the microparticles at least portion of which are attached to the surface of the adhesive region, wherein the therapeutic agent is not partially or fully embedded within the microparticles as required by the amended claims.

In response to this argument, applicant attention is directed to the abstract of the US '617 that clearly disclosed that the therapeutic agents are on the surface of the microparticles, so are not embedded either partially or fully into the microparticles as required by the instant claims. Further the method of applying the microparticles and active agents on the articles disclosed by the reference are the same as disclosed by applicants, therefore, therapeutic agents are applied by spraying or dipping will remain on the surface and not embedded into the microparticles or the device.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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